

### Remarks/Arguments

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed December 23, 2008. Currently, claims 1-5, 8, 13-15, 19-23, and 28-31 remain pending. Claims 1-5, 8, 13-15, 19-23, and 28-31 have been rejected. Favorable consideration of the following remarks is respectfully requested.

#### ***Claim Rejections – 35 USC § 103***

In paragraph 5 of the Final Office Action, claims 1-5, 8, 13-15, 19-23, and 28-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. Patent No. 6,099,497). After careful review, Applicant must respectfully traverse this rejection.

Turning to claim 1, which recites:

1. (Previously Presented) A catheter system for positioning a stent at a vessel bifurcation, the catheter system comprising:
  - a catheter, the catheter comprising:
    - a channel having a main guidewire lumen extending proximally from a distal end of said catheter to a main exit port, said main exit port located at a first distance from said distal end, wherein said main guidewire lumen is configured to receive a main vessel guidewire therethrough; and
    - a branch guidewire enclosure positioned alongside said channel, wherein said branch guidewire enclosure is configured to receive a branch vessel guidewire therethrough; and
  - a stent having a lumen and a side opening in a wall thereof, said stent positioned on a distal portion of said channel, and wherein a distal portion of said branch guidewire enclosure is positioned through said lumen and exiting at said side opening,
  - said branch guidewire enclosure extending proximally from said side opening of said stent to a branch exit port, said branch exit port located at a second distance from said distal end of said catheter system, said branch guidewire enclosure bonded to said channel only at said branch exit port, said first distance and said second distance being substantially equal,
  - wherein said first distance and said second distance are less than a distance from said distal end of said catheter system to a proximal end of said catheter system and greater than a distance from said distal end of said catheter system to said proximal end of said stent.

In the Final Office Action, the Examiner appears to acknowledge that Adams “does not explicitly disclose that the branch guidewire enclosure is bonded to the channel *only* at said branch exit port or only at the three way bond”. However, the Office Action continues to state

that the mode of bonding the enclosure to the catheter is a matter of obvious design choice. Applicant must respectfully disagree.

Design choices are discussed in the Manual of Patent Examining Procedure (MPEP) § 2144.04(VI)(C), but only insofar that they constitute a rearrangement of parts. MPEP § 2144.04(VI)(C) states:

*C.Rearrangement of Parts*

*In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (Claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). However, “The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of applicant’s specification, to make the necessary changes in the reference device.” *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

(Emphasis added). From this passage, it appears that a mere rearrangement of parts is an obvious design choice unless the rearrangement would have modified the operation of the device. Further, it appears that “the mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims … is not by itself sufficient to support a finding of obviousness”, but that the prior art must provide a motivation or reason for the rearrangement.

Applicant must respectfully assert that “said branch guidewire enclosure bonded to said channel *only* at said branch exit port” modifies the operation of the device. For example, page 8, line 32 through page 9, line 4 of the application, provides some examples of how the claimed limitation may modify the operation of the device, such as the flexibility and stiffness characteristics of the catheter system. Page 8, line 32 through page 9, line 4 recites:

By distancing the balloon and stent from bond portion 24 (by around 10 cm or more), more flexibility in rotation of the system is provided, facilitating rotational alignment of side opening 34 of stent 32 with the ostium of the branch vessel. Furthermore, stiffness in the area of the stent is reduced by not having extra bond material present in the general region of the stent.

As is readily apparent from this passage, the limitation “said branch guidewire enclosure bonded

to said channel *only* at said branch exit port" can provide for more flexibility in rotation of the system facilitating rotational alignment of side opening of stent with the ostium of the branch vessel. Additionally, the limitation "said branch guidewire enclosure bonded to said channel *only* at said branch exit port" may also provide for a reduced stiffness in the area of the stent. Accordingly, it is believed that the limitation "said branch guidewire enclosure bonded to said channel *only* at said branch exit port" modifies the operation of the claimed catheter system.

Further, nothing in Adams et al. appear to provide any motivation or reason for modifying the device of Adams et al. to have "said branch guidewire enclosure bonded to said channel *only* at said branch exit port", as is required according to MPEP § 2144.04(VI)(C). Accordingly, Applicant must respectfully assert that "said branch guidewire enclosure bonded to said channel *only* at said branch exit port" is not a mere design choice. Therefore, for at least these reasons, claim 1 is believed to be patentable over Adams et al. For similar reasons and others, claims 2-5 and 8, which depend from claim 1 and include additional limitations, are believed to be patentable over Adams et al.

Turning to claim 13, which recites:

13. (Previously Presented) A catheter comprising:  
a proximal tube terminated at a distal end;  
a distal assembly comprising a first tube terminated at a proximal end and a second tube terminated at a proximal end, wherein said first tube is configured to receive a first guidewire and said second tube is configured to receive a second guidewire; and  
a three-way bond coupling the distal end of the proximal tube to said proximal end of said first tube and to said proximal end of said second tube; wherein the second tube of the distal assembly is bonded to the first distal tube only at the three-way bond.

As discussed previously, nowhere does Adams et al. appear to teach or suggest "wherein the second tube of the distal assembly is bonded to the first distal tube only at the three-way bond" and Applicant must respectfully assert that this limitation is not a mere design choice. Therefore, for at least these reasons, claim 13 is believed to be patentable over Adams et al. For similar reasons and others, claims 13-15 and 19-23, which depend from claim 13 and include additional limitations, are believed to be patentable over Adams et al.

Turning to claim 28, which recites:

28. (Previously Presented) A catheter comprising:  
a proximal tube extending from a proximal end to a distal end;

- a first distal tube having a proximal open end, the first distal tube being configured to receive a first guidewire;
- a second distal tube having a proximal open end, the second distal tube being configured to receive a second guidewire; and
- a bond having a proximal end and a distal end, the proximal end of the bond connecting to the proximal tube at the distal end of the proximal tube, the distal end of the bond connecting to the first distal tube at the proximal open end of the first distal tube, and the distal end of the bond connecting to the second distal tube at the proximal open end of the second distal tube, wherein the second distal tube is detached from the first distal tube outside of the bond.

As discussed previously, nowhere does Adams et al. appear to teach or suggest “wherein the second distal tube is detached from the first distal tube outside of the bond” and Applicant must respectfully assert that this limitation is not a mere design choice. Therefore, for at least these reasons, claim 28 is believed to be patentable over Adams et al. For similar reasons and others, claims 29-31, which depend from claim 28 and include additional limitations, are believed to be patentable over Adams et al.

### ***Conclusion***

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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